

### **AMENDMENTS TO THE CLAIMS**

Please amend claims 1, 3, 4, 7, 10, 11 and 21, and cancel claims 2, 5, 6, 13-15 and 18-20 as indicated in the Listing of Claims below, which replaces all prior versions of claims in the application.

### **LISTING OF CLAIMS**

1. (currently amended) A tracheotomy valve unit adapted to cooperate with a tracheotomy tube inserted into a patient's trachea, said valve unit comprising:
  - a. a first end comprising a connector adapted for connection to the free end of the tracheotomy tube and a valve base adapted to receive the connector;
  - b. a second end comprising a valve unit inlet, the valve unit inlet comprising a support comprising a crosspiece configured to form air ports therethrough and a disk-shaped member defining a hole therethrough;
  - c. a first valve comprising a seating ring extending inward from the support around the outer periphery of the air ports, a thin, flexible diaphragm biased against the seating ring and making positive closure contact therewith, and a rivet for connecting the diaphragm to the seating ring, the rivet adapted to sealingly fit into the hole defined by the disk-shaped member and having a length to bias the diaphragm against the seating ring, that wherein the first valve permits airflow from the valve unit inlet through the valve unit and to the tube in the patient's trachea when the patient inhales, and blocks airflow from the tube through the valve unit when the patient exhales; and
  - d. a second valve located in an axial bore hole of the rivet and operable to open during pressures associated with speaking, wherein the second valve begins to open to permit that permits airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 3 cm of water, allows increasing airflow through it as the intrathoracic pressure during expiration increases, is fully open and allows maximum airflow therethrough when the intrathoracic pressure reaches about 12 cm of water, and

blocks such airflow when the intrathoracic pressure during expiration is less than about 3 cm of water.

2. (canceled)
3. (currently amended) The valve unit of claim 1 2 wherein the diaphragm is made of silicone sheet material.
4. (currently amended) The valve unit of claim 1 2 wherein the diaphragm is biased against the seating ring by a pressure of from about 8 to about 15 mm of water head.
5. (canceled)
6. (canceled)
7. (currently amended) The valve unit of claim 1 6 wherein the second valve comprises a slit valve or an umbrella valve.
8. (original) The valve unit of claim 7 wherein the diaphragm is biased against the seating ring by a pressure of from about 8 to about 15 mm of water head.
9. (original) The valve unit of claim 8 wherein the diaphragm is made of low-modulus silicone sheet material.
10. (currently amended) The valve unit of claim 9 wherein the second valve begins to open to permit permits airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 4 cm of water, allows increasing airflow through it as the intrathoracic pressure during expiration increases, is fully open and allows maximum airflow therethrough when the intrathoracic pressure

reaches about 10 cm of water, and blocks such airflow when the intrathoracic pressure during expiration is less than about 4 cm of water.

11. (currently amended) The valve unit of claim 1 wherein the second valve begins to open to permit permits airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 4 cm of water, allows increasing airflow through it as the intrathoracic pressure during expiration increases, is fully open and allows maximum airflow therethrough when the intrathoracic pressure reaches about 10 cm of water, and blocks such airflow when the intrathoracic pressure during expiration is less than about 4 cm of water.
12. (original) The valve unit of claim 11 wherein the second valve comprises a slit valve or an umbrella valve.
13. (canceled)
14. (canceled)
15. (canceled)
16. (original) The valve unit of claim 1 wherein the second valve begins to open to permit airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is about 4 cm of water, and is fully open when the intrathoracic pressure during expiration is about 10 cm of water.
17. (original) The valve unit of claim 16 wherein the second valve comprises a slit valve or an umbrella valve.
18. (canceled)

19. (canceled)
20. (canceled)
21. (currently amended) A tracheotomy valve unit adapted to cooperate with a tracheotomy tube inserted into a patient's trachea, said valve unit comprising:
  - (a) a first end adapted for connection to the free end of the tracheotomy tube;
  - (b) a second end comprising a valve unit inlet, the valve unit inlet comprising a support comprising a crosspiece configured to form air ports therethrough and a disk-shaped member defining a hole therethrough;
  - (c) a first valve that permits airflow from the valve unit inlet through the valve unit and to the tube in the patient's trachea when the patient inhales, and blocks airflow from the tube through the valve unit when the patient exhales, said first valve comprising a seating ring extending inward from the support around the outer periphery of the air ports, a thin, flexible diaphragm biased against the seating ring, thereby making positive closure contact therewith, and a rivet for connecting the diaphragm to the seating ring, the rivet adapted to sealingly fit into the hole defined by the disk-shaped member and having a length to bias the diaphragm against the seating ring; and
  - (d) a second valve that begins to open to permit airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 3 cm of water, is fully open when the intrathoracic pressure reaches about 12 cm of water, and blocks such airflow when the intrathoracic pressure during expiration is less than about 3 cm of water, wherein the second valve comprises a slit valve or an umbrella valve that is located in an axial bore hole of the rivet.
22. (original) The valve unit of claim 21 wherein the diaphragm is made of low-modulus silicone sheet material.

23. (previously presented) The valve unit of claim 22 wherein the second valve begins to open to permit airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 4 cm of water, is fully open when the intrathoracic pressure reaches about 10 cm of water, and blocks such airflow when the intrathoracic pressure during expiration is less than about 4 cm of water.
24. (original) The valve unit of claim 22 wherein the second valve begins to open to permit airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is about 4 cm of water, and is fully open when the intrathoracic pressure during expiration is about 10 cm of water.
25. (original) The valve unit of claim 24 wherein the second valve allows increasing airflow through it as the intrathoracic pressure during expiration increases beyond 4 cm of water until maximum airflow is achieved at a pressure of about 10 cm of water.